

tropicil top®

Tropicamide 0.5% and 1%

5 mg/ml eye drops, solution
10 mg/ml eye drops, solution

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Tropicil Top is and what it is used for
2. Before you use Tropicil Top
3. How to use Tropicil Top
4. Possible side effects
5. How to store Tropicil Top
6. Further information

1. WHAT TROPICIL TOP IS AND WHAT IT IS USED FOR

Tropicil Top 5 mg/ml is an eye drops solution whose only active ingredient is tropicamide at the concentration of 5 mg/ml.
Tropicil Top 10 mg/ml is an eye drops solution whose only active ingredient is tropicamide at the concentration of 10 mg/ml.

Tropicamide is an anticholinergic agent used to block the responses of the iris sphincter muscle and the accommodation response of the ciliary body's muscle to the acetylcholine stimulation.
The 5 mg/ml solution causes the pupillary dilatation (mydriasis).
The 10 mg/ml solution causes mydriasis as well as paralysis of the transitory accommodation (cycloplegia).

Therapeutic Indications:

- Mydriasis for performing ophthalmological exams;
- Therapeutic mydriasis.

2. BEFORE YOU USE TROPICIL TOP

Do not use TROPICIL TOP

If you are allergic (hypersensitive) to tropicamide or to any of the other ingredients of Tropicil Top. In patients suffering from closed-angle glaucoma, there is a risk of closing the chamber angle and of precipitating a glaucomatous crisis.

Take special care with Tropicil Top

Avoid repeated instillations. The risk/benefit ratio should be taken into account when using this medicine in children with brain damage or with spastic paralysis. This ratio should also be considered in cases of Down syndrome or mongolism or predisposition to closed-angle glaucoma. Although the possibility of tropicamide's systemic action in ophthalmic use is remote, the particular sensitivity of children and debilitated people to antimuscarinic drugs should always be kept in mind. Since the use of this medication causes pupil dilation, an exaggerated sunlight sensitivity is normal. The use of sunglasses (ultraviolet blocking glass) can be helpful.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.
The effects of tropicamide on the fetus, when administered to pregnant women, are not known. Tropicamide should only be administered to pregnant women if the potential benefit overcomes the potential risk to the fetus.
The excretion of tropicamide in breast milk is unknown. Since many drugs are excreted into breast milk, tropicamide should be administered with precaution during amamentation.

Driving and using machines

It is inadvisable to drive cars or to operate machinery after using the eye drops.

Important information about some of the ingredients of Tropicil Top

Tropicil Top contains thiomersal: may cause allergic reactions.

3. HOW TO USE TROPICIL TOP

Always use Tropicil Top exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
The posology of Tropicil Top should be established by the doctor according to each case.

As a cycloplegic agent, the usual dose is two drops of Tropicil Top 10 mg/ml, every 5 minutes, for a refraction study. The eye should be observed 20 to 40 minutes after applying the second drop.
As a mydriatic agent, for deep ocular exam, the usual dose is one to two drops of Tropicil Top 5 mg/ml, on the eye to be observed. To keep the mydriasis for a longer period of time, it is necessary to instill one more drop every 30 minutes.

The eye drops should be applied in the conjunctival sac, the space between the eye and the eyelid.

You should avoid repeated instillations of the eye drop.

If you use more Tropicil Top than you should

Overdose manifests the exacerbation of the possible side effects.
Physostigmine is the antidote for the systemic effects of this medicinal product.

If you forget to use Tropicil Top

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Tropicil Top can cause side effects, although not everybody gets them.

Side effects:

Increased intraocular pressure. Psychological and behavioral disorders and other systemic reactions have been reported in children. The following side effects may occur: transient stinging sensation, dry mouth, prolonged dilation of the pupil hindering the vision, fotobia, tachycardia, headache, parasympathetic stimulation or allergic reactions.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE TROPICIL TOP

- Do not store above 25°C;
- Keep out of the reach and sight of children;
- Do not use Tropicil Top after the expiry date which is stated on the label and on the carton after "EXP". The expiry date refers to the last day of that month;
- Use Tropicil Top within 28 days, after first opening the bottle;
- Do not use Tropicil Top if there are visible signs of deterioration;
- Being a medicine for ophthalmic use only, it shouldn't be given any other use to its dropper bottle;
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Tropicil Top contains

The active substance is tropicamide.
The other ingredients are: boric acid, thiomersal, propylene glycol, highly purified water, hydrochloric acid concentrated, sodium chloride (for osmolality adjustment) and sodium hydroxide (for pH adjustment).

What Tropicil Top looks like and contents of the pack

Tropicil Top is an eye drops solution with clear, colorless and odorless appearance.
Tropicil Top is supplied sterile in LDPE dropper bottles containing 10 ml of eye drops solution.

Marketing Authorisation Holder and Manufacturer

Laboratório Edol - Produtos Farmacêuticos, S.A.
Av. 25 de Abril, 6
2795-195 Linda-a-Velha
Portugal
tel: +351 21 415 81 30
fax: +351 21 415 81 31
e-mail: geral@edol.pt

This leaflet was last approved on 09/2010.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines their benefits and risks.
- Do not by your-self interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of the children.

Council of Arab Health Minister,
Union of Arab Pharmacists

edol®

Laboratório Edol - Produtos Farmacêuticos, S.A.
Av. 25 de Abril, 6
2795-195 Linda-a-Velha